

MONTANA STATE HOSPITAL POLICY AND PROCEDURE

DIETARY SUPPLEMENT POLICY

Effective Date: March 31, 2003 Policy #: PH-02

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I. **PURPOSE:** To establish a mechanism to ensure that patients at Montana State Hospital receive medications that are proven to be both safe and effective as set forth by FDA standards.

II. POLICY:

- A. Dietary supplements come in many forms, including tablets, capsules, powders, softgels, gelcaps, and liquids. Though commonly associated with health food stores, dietary supplements also are sold in grocery, drug and national discount chain stores, as well as through mail-order catalogs, TV programs, the Internet, and direct sales.
- B. Dietary supplements are not drugs. A drug, which sometimes can be derived from plants used as traditional medicines, is an article that, among other things, is intended to diagnose, cure, mitigate, treat, or prevent diseases. Before marketing, drugs must undergo clinical studies to determine their effectiveness, safety possible interactions with other substances, and appropriate dosages. The FDA must review this data and authorize the drugs' use before they are marketed. FDA does not authorize or test dietary supplements.
- C. Montana State Hospital has no way of determining priority, safety, or effectiveness of substances not FDA approved.

III. DEFINITIONS:

A. <u>Dietary Supplements</u> - Dietary supplements refer to products made of one or more of the essential nutrients, such as vitamins, minerals and protein. The Dietary Supplement Health and Education Act (DSHEA) broadens the definition to include, with some exceptions, any product intended for ingestion as a supplement to the diet. This includes vitamins; minerals; herbs; botanicals and other plant-derived substances; and amino acids (the individual building blocks of protein) and concentrates, metabolites, constituents and extracts of these substances.

IV. RESPONSIBILITIES:

A. Physicians and nursing staff are responsible for abiding by this policy.

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V. PROCEDURE:

- A. The use of dietary supplements not approved by FDA is prohibited at Montana State Hospital.
- VI. REFERENCES: FDA Guidelines
- VII. COLLABORATED WITH: Pharmacy Director, Dietary Services Manager
- **VIII. RESCISSIONS:** #PH-02, *Dietary Supplement Policy* dated February 14, 2000; HOPP #PH-08-97-N, Herbal Policy, dated March 7, 1997.
- **IX. DISTRIBUTION:** All hospital policy manuals.
- X. REVIEW AND REISSUE DATE: March 2006
- XI. FOLLOW-UP RESPONSIBILITY: Medical Director
- XII. ATTACHMENTS: None

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Ed Amberg	Date	Thomas Gray, MD	Date
Hospital Administrator		Medical Director	